Environmental Assessment for (Hsp_2O)® Solution in Support of an FCN Regarding the Use of Hypochlorous Acid to Disinfect Water Used to Crisp Vegetables with Draining

1. Date:
Prepared April 16, 2012

2. Name of Submitter:
HSP USA, LLC

3. Address:

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4. Description of Proposed Action:

a. Requested Action:

This FCN is seeking an approval for the use of a food-contact substance for re-hydrating fresh produce at retail and food service establishments:

- Introduction of 20 gals of a (Hsp_2O)® solution at up to 60 ppm available free chlorine (AFC) in a produce sink consistent with the preconditions outlined in the Food Code.
- Place 1 box of leafy greens or other whole uncut produce item in increments of five (5) pound loads into the sink to soak for a minimum of 5 minutes.
- Remove produce and set aside to drain
- Test (Hsp_2O)® solution for AFC and if above 25 ppm charge the sink with another five (5) pounds of produce. If AFC is below 25 ppm, drain the sink and re-fill with fresh (Hsp_2O)® solution.
- Continue until all the produce requiring crisping is complete.
- Produce may be used for display or prepared for consumption after 10 minutes of draining.

b. Need for action:

The intended technical effect of eliminating a potable water rinse is to avoid cross contamination of re-crisped product or products. Looking specifically at lettuce re-crisping as an example, if lettuce is re-crisped or rinsed by placing fresh-cut lettuce/leafy greens in containers with tap water or other water with a low level of chlorine, the chlorine present is quickly inactivated by the organic load presented by the lettuce/leafy greens. This will increase the potential for lettuce/leafy greens cross contamination particularly if additional lettuce/leafy greens are added to the container (Wachtel and Charkowski, 2002 Attachment A).

The ability of chlorine to prevent cross contamination in aqueous baths was illustrated with inoculated cantaloupes and Salmonella (Suslow 2004 Attachment B). This report clearly shows that Salmonella migrated when fruit was soaked in water. By analogy and experience, the treatment of lettuce will not fully disinfect the lettuce. All subsequent treatment of lettuce with water without benefit of chlorine will promote both cross contamination and spread of existing contamination within the head.

c. Locations of use/disposal:

$(Hsp_2O)^{®}$ solution for re-hydrating fresh produce at retail will generally be used in the backroom of the store where produce is prepared. Given that crisping is done in a sanitary sink, disposal will be through the sanitary sewer.

5. Identification of substances that are subject to the proposed action:

$(Hsp_2O)^{®}$ solution is a hypochlorous solution made from a tightly controlled chemical process (See Attachment K – Confidential Business Information. Hypochlorous acid (7790-92-3) is the active component and will generally be present at at or below 60 ppm for treatment.Residual sodium chloride (7647-14-5) is also present as a result of the reaction.

The formula for hypochlorous acid is HOCl. Its molecular weight is 52.46. Concentrated hypochlorous acid is greenish-yellow in solution. In its concentrated form hypochlorous acid is highly unstable and decomposes to hydrogen chloride and oxygen except in dilute solution. $(Hsp_2O)^{®}$ solution is generated on site as needed.

6. Introduction of substances into the environment:

a. Introduction of substances into the environment as a result of manufacture:

No extraordinary circumstances apply to the generation of $(Hsp_2O)^{®}$ solution. It is generated on site in accordance with demand. The generation process releases hypochlorous acid in a very weak brine solution

b. Introduction of substances into the environment as a result of

use/disposal:

The released materials from the procedure include sodium chloride brine, residual available chlorine, and low levels of by-products including chlorate, chlorite, and disinfection by-products that are associated with the use of the various forms of chlorine.

To estimate the potential discharge volumes associated with the proposed process, it is sufficient to have a projected number of units to be installed, a projected usage rate and the measured concentrations of the various components and by-products in the discharge. The calculations require simple multiplications of the concentrations, the number of 20 gallon cycles per day (See Confidential Business Information), the number of days per year (365) and the projected number of installations (See Confidential Business Information). The calculations and results are reported in Attachment K, Confidential Business Information.

The expected concentrations of the various constituents and by-products have been measured and reported in the various studies and other information associated with this FCN. The discharged weak brine will be the dominant component besides water at less than 0.005% sodium chloride.

The discharged brine solutions will also contain modest levels of free available chlorine depending on the amount of treated produce ranging from essentially zero to 60 ppm if no produce is treated. The average discharge is expected to be less than 25ppm based on the process guideline of reusing solutions greater than 25 ppm and discharges those solutions which are less than 25 ppm. This residual chlorine can be expected to rapidly react (less than 3 hours) with organic material in the waste stream producing mostly oxygen and chloride. For the minor components and by-products, the chlorite levels will be less than 0.3 ppm. This estimate is based on the detection limit as no chlorite was detected experimentally. The chlorate levels will be less than 2 ppm. And finally, the total trihalomethanes, representative of the disinfection by-products, will be between 20-50 ppb. These discharge concentrations are the same as those in FCN No. 692. These concentrations are used to estimate annual discharges which are reported in Attachment K, Confidential Business Information.

Virtually 100% of these materials will enter the waste stream via the sanitary sewer at the retail store.

7. Fate of substances released into the environment:

All of the components of $(Hsp_2O)^{®}$ solution and the degradation products are well known and with the exception of the sodium chloride are at levels approximating those found in drinking water. The proposed process does not increase or decrease the discharges from the allowed process.

This said, sodium chloride is exceedingly stable in the environment. It will become part of the total dissolved solids (TDS) in the effluent stream from the wastewater treatment facility. Furthermore, because oxychlorine species (hypochlorous acid, chlorite, chlorate and chlorine dioxide) readily react with the organic matter and microorganisms in water and soil (sediments) and will undergo ultimate degradation into chloride ion, we anticipate that the expected environmental concentrations for these oxychlorine species will be very small and thus will be of no environmental concern. **(**Attachment C**,** Supplement to the Environmental Information for Food Contact Notification No. 450, October 18, 2004, Tong Zhou, Ph.D., Environmental Toxicologist Environmental Review Group Division of Chemistry Research and Environmental Review)

Given that the $(Hsp_2O)^{®}$ solutions will be discharged to a sanitary sewer after use where the total stream is generally chlorinated, the discharges from this process will rapidly be lost in these larger pools. Furthermore, when a chlorinated effluent is released into receiving waters, free residual chlorine dissipates rapidly. It has a half-life of 1.3 to 5 hours (Attachment D, EPA RED for Chlorine Gas). The ultimate fate of chlorine-containing effluent is site specific, and depends on factors such as the chemical constituents of the receiving waters, their temperature, the dilution ratio and the intensity of sunlight (Attachment D, EPA RED for Chlorine Gas). The disinfection by-products such as the trihalomethanes are the same materials found in chlorinated drinking water, at levels well within the drinking water standard and will share the same fate as these larger pools of material in the wastewater effluent.

8. Environmental effect of released substances:

We reviewed information on www.pesticideinfo.org and have identified ecotoxicology studies on fish and zooplankton species for the expected effluent components. Among these are chlorite studies for opossom shrimp, sodium chloride studies on water flea (*Ceriodaphnia dubia*) as well as hypochlorous acid studies on rainbow trout. The findings are summarized in the table below:

No.	Compound	Organism	Effect	Measurement	Life Stage	Study Time	Endpoint	Toxic Dose (ug/L)
1	Hypochlorous Acid	Oncorhynchus mykiss	Mortality	Mortality	156-169 MM	2h	LC 50	200
2	Sodium Chloride	Ceriodaphnia dubia	Mortality	Mortality	<24h	7d	LC 50	330,000
3	Sodium Chlorite	Americamysis bahia	Mortality	Mortality	<24h	96h	LC 50	576 (mean)
4	Sodium Chlorate	Daphnia magna	Mortality	Mortality	NR	48h	LC 50	3,162,000

Uses of hypochlorous acid that are **not** regulated under the NPDES permit program, include swimming pool, aquaria and indoor use patterns (fruit and vegetable rinsing and food processing), should produce only intermittent discharges of minimal concentration into lakes or streams, resulting in minimal environmental exposure." (Attachment F EPA RED Facts Chlorine Gas)

The Estimated Environmental Concentrations (EECs) from the proposed use for all species will be many orders of magnitude less than the levels discharged to the sewer at the point of use. This estimate can be rationalized by assuming a retail store provides produce for up to 10,000 people (Estimate based on Milpitas, CA with about 70,000 people and 7 retail stores). The total water discharge in Milpitas is 18.5 million gallon per day (Attachment E, Clean Watershed Need Survey).

The Estimated Environmental Concentrations (EECs) are summarized as follows based on the assumptions above. See Attachment K, Confidential Business Information for detailed calculations.

No.	Compound	ECCs (µg/L)
1	Hypochlorous Acid	1.8
2	Sodium Chloride	3.8
3	Sodium Chlorite	0.023
4	Sodium Chlorate	0.15

With the 4 to 5 orders of magnitude of dilution, EECs are significantly below the endpoints for all four

concerned substances. In addition, the short half-life of hypochlorous acid will further reduce its EEC once it enters the sanitary sewer. The environmental effects of the released substances will be insignificant.

The data available strongly suggests that the amounts of the oxychlorine species which would be expected to be released into the environment as a bi-product of using $(Hsp_2O)^{®}$ solution to crisp leafy vegetables through the use and disposal would be so low as to pose no threat to either aquatic or terrestrial ecosystems.

9. Use of resources and energy:

The proposed change will have essentially no effect on resources or energy. The use of draining to remove residual chlorine will provide a very minor reduction in water use. All other factors would remain the same.

10. Mitigation measures:

No adverse situations requiring mitigation have been identified.

11. Alternatives to the proposed action:

No adverse environmental impacts remain to be addressed so alternatives are not required.

12. List of preparers:

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Mr. Dao has over nineteen years of experience in the management consulting, process engineering and manufacturing. He has consulted with clients including healthcare, food and beverage, water treatment, industrial products and chemicals, and many other industrial or commercial fortune 500 companies. As the President and CEO, Mr. Dao has the overall responsibility in setting strategic direction and tactical management of the firm. In addition, Mr. Dao is passionate about and active in promoting clean technology and economic development focused initiatives.

13. Certification:

The undersigned official certifies that the information presented is true, accurate and complete to the best of the knowledge of HSP USA, LLC.

_4/17/12_ _____

(Date)

[redacted]

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(Signature) Henry Dao, President / CEO

14. References:

A. Marian R. Wachtel and Amy O. Charkowski, Cross-Contamination of Lettuce with *Escherichia coli* O157:H7, Journal of Food Protection, Vol. 65, No. 3, 2002, Pages 465–470

B. Trevor V. Suslow, Minimizing the Risk of Food Borne Illness Associated with Cantaloupe Production and Handling in California, Regents of the University of California, 2004

C. Tong Zhou , Supplement to the Environmental Information for Food Contact Notification No. 450, October 18, 2004, Environmental Toxicologist Environmental Review Group Division of Chemistry Research and Environmental Review)

D. *Reregistration Eligibility Decision (RED): Chlorine Gas*; EPA738-R-99-001; Office of Pesticide Programs; US EPA: February 1999, http://www.epa.gov/oppsrrd1/REDs/4022red.pdf

E. Clean Watersheds Needs Survey – Discharge Database 2000 for Santa Clara County, Environmental Protection Agency, http://cfpub.epa.gov/cwns/rpt_discharge2_00.cfm

F. Registration Eligibility Decision (RED) Facts : Chlorine Gas, EPA-738-F-99-001, US EPA, February 1999 http://www.epa.gov/oppsrrd1/REDs/factsheets/4022fact.pdf

G. Chlorine Dioxide: Final Risk Assessment Case 4023; Docket ID No. EPA-HQ-OPP-2006-0328; U.S. Environmental Protection Agency, Antimicrobials Division: Washington, D.C., Aug 2, 2006.

H. James Ringo, Sodium chlorite environmental Assessment, Biocide International, August 27, 2004, http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/UCM143218.pdf

I. Ambient Water Quality Criteria for Chloride-1988, EPA 440/5-88-001, US EPA , February 1988, http://www.epa.gov/waterscience/pc/ambientwqc/chloride1988.pdf

J. Ambient Water Quality Criteria for Chloroform EPA 440/5-80-033, US EPA, October 1980 http://www.epa.gov/waterscience/pc/ambientwqc/chloroform80.pdf

15. Attachments:

A. Wachtel and Charkowski, 2002, (The data was part of FCN 692 and is therefore not included)

B. Suslow, 2004 (The data was part of FCN 692 and is therefore not included)

C. Supplemental for FCN No. 450 (The data was part of FCN 692 and is readily available on the web and is therefore not included)

D. EPA RED for Chlorine Gas (The data was part of FCN 692 and is readily available on the web and is therefore not included)

E. Clean Watersheds Need - Santa Clara County (The data was part of FCN 692 and is readily available on the web and is therefore not included)

F. EPA RED Factsheet for Chlorine Gas (The data was part of FCN 692 and is readily available on the web and is therefore not included)

G. Chlorine Dioxide Final Risk Assessment (The data was part of FCN 692 and is readily available on the web and is therefore not included)

H. Sodium chlorite Environmental Assessment (The data was part of FCN 692 and is readily available on the web and is therefore not included)

I. Water Quality Criteria -Chloride (The data was part of FCN 692 and is readily available on the web and is therefore not included)

J. Water Quality Criteria -Chloroform (The data was part of FCN 692 and is readily available on the web and is therefore not included)

K. Confidential Business Information